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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,972	01/23/2004	Mark David Fidock	PC10960B	8280

28523 7590 11/30/2004
PFIZER INC.
PATENT DEPARTMENT, MS8260-1611
EASTERN POINT ROAD
GROTON, CT 06340

EXAMINER

LI, RUIXIANG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/763,972

Applicant(s)

FIDOCK, MARK DAVID

Examiner

Ruixiang Li

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-20 is/are pending in the application.
- 4a) Of the above claim(s) 9 and 11-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-8 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 10/023,586.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 09/17/2004.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☒ Other: Sequence alignment.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-8 and 10, in the reply filed on September 17, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Applicants' preliminary amendment filed on September 17, 2004 has been entered. Claims 2 and 3 have been canceled. Claims 1, 4, and 10 have been amended. Claims 1 and 4-20 pending. Claims 1, 4-8, and 10 are under consideration. All other claims are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Priority

3. Acknowledgment is made of a claim for domestic priority under 35 U.S.C. 119(e) to provisional applications 60/260,563 (filed on 01/09/2001) and 60/265,688 (filed on 02/01/2001).

Acknowledgment is also made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been received in application 10/023,586

Drawings

4. The drawings filed on 01/23/2004 are accepted by the Examiner.

Information Disclosure Statement

5. The information disclosure statement filed on 09/17/2004 has been considered by the Examiner and a signed copy of the form PTO-1449 is attached to the office action.

Rejections—35 USC § 101

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 1, 4-8, and 10 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

Claims 1, 4-8, and 10 are drawn to an isolated polynucleotide, a vector, a host cell, and a method of producing a polypeptide encoded by the polynucleotide. The claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. A specific and substantial utility is one that is particular to the subject matter claimed and that identifies a "real world" context of use for the claimed invention which does not requires further research.

The invention is based upon the discovery of PFI-020 nucleic acid sequence by bioinformatics analysis. The specification asserts that PFI-020 nucleic acid sequence encodes a encoding a G-protein coupled receptor whose ligand is likely to

be a nucleotide or a nucleotide derivative and that the PFI-020 polypeptide is most similar to purinergic receptors and (page 16). The specification further discloses PFI-020 polypeptide activation by various purinoceptor agonists in a FLIPR cell-based assay (Example 5; Figures 3-6). Nonetheless, the specification fails to disclose the specific biological functions or any physiological significance of the PFI-020 and fails to disclose a specific and substantial utility for the claimed invention. Thus, one skilled in the art would not be able to recognize the use of the claimed invention in its currently available form and to know what to do with the claimed nucleic acids.

The specification asserts that the present invention provides agonists and antagonists of the polypeptides of the present invention, which are useful in treatment of a list of numerous diseases (pages 6-7 of specification). However, these asserted utilities are not specific and substantial because they do not identify or reasonably confirm a "real world" context of use. The specification neither identifies the biological functions of the polypeptides or nucleic acids of the present invention nor any diseases that are associated with the molecules of the present invention. Clearly, further research would be required to determine the functions of the claimed molecules or to identify a disease that can be treated or diagnosed with the claimed molecules. See *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966), noting that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."

The specification further asserts the utilities of polynucleotides as primers or hybridization probes (page 12, last paragraph). However, such uses are all

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considered research uses only designed to identify a particular function of the claimed molecules and are not a substantial utility. See, e.g., *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966) wherein a research utility was not considered a "substantial utility." Moreover, such uses are not specific to the instant molecule but applicable to any nucleic acid molecules.

The invention also lacks a well-established utility. A well-established utility is a specific, substantial, and creditable utility that is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material. The sequence homology of the amino acid sequence of PFI-020 with the purinergic receptors (Fig. 2 and page 16) does not endow the claimed nucleic acids with a specific and substantial utility because members of purinergic receptors have diverse structures and biological functions (see, e.g., Harden et al, *Annu. Rev. Pharmacol. Toxicol.* 35: 541-579, 1995; Bhagwat et al, *Eur. J. Med. Chem.* 32:183-193, 1997) and the functions of each receptor need to be determined individually. Even the specification acknowledges that there are several diverse families of receptors, which respond to purine and pyrimidines (4th paragraph of page 2). No art of record discloses or suggests any property or activity for the claimed molecules such that another non-asserted utility would be well-established for the compounds.

8. Claims 1, 4-8, and 10 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections—35 USC § 112, 2nd paragraph

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 7 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is indefinite because it is unclear what protein is to be made; the claim, as written, reads on any proteins produced by the cell.

Claim 10 is indefinite because it recites “a membrane preparation of the cells”. It is unclear whether applicants intend to claim a preparation of the polypeptide of SEQ ID NO: 2 or a membrane preparation that does not necessarily comprise the polypeptide of SEQ ID NO: 2. For example, in E. coli cells, the majority of the polypeptide would be present in inclusion bodies.

Claim Rejections—35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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12. Claims 1, 4-8, and 10 are rejected under 35 U.S.C. §102(e) as being anticipated by Ramakrishnan (WO200185764-A2, pub. Date: November 15, 2001; filing date: May 9, 2001; earliest 102 (e) date: May 11, 2000).

Ramakrishnan teaches an isolated polynucleotide that encodes the amino acid sequence of SEQ ID NO: 2 (see attached sequence alignment). Ramakrishnan also teaches a nucleic acid vector comprising the nucleic acid molecule, a host cell (including mammalian cells; page 23) containing the vector, and a method for producing a polypeptide. Ramakrishnan further teaches membrane preparation of the cells (page 72, line 5; page 75, line 19). Therefore, the reference of Ramakrishnan meets the limitations of claims 1, 4-8, and 10.

Conclusion

13. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

Ruixiang Li

Ruixiang Li, Ph.D.
Examiner
November 29, 2004

QY	261	ProAspGhi	ProThrGly	Val	TP	ProLeu	His	ProLeu	Phe	Cys	Ala	Leu	Pro	Tyr	His	280		
DB	897	CGGACCA	CTCTACT	GGTGT	GTGGCC	TCT	CA	CCCTCT	GT	TTTTGT	GGCCCT	TCC	ATA	TCA	C	955		
QY	281	SerLeu	Leu	Pro	His	Leu	Ser	Ala	Phe	Ser	Gly	Leu	Pro	Ala	Leu	Asp	Gly	300
DB	957	TCGCTCT	TTCTAC	CTC	CA	CCATC	CTG	CTTTCT	CAG	ACT	GCC	AGT	CTT	GAT	GCC	1016		

QY 301 ~~ser~~gincysgylteuginhspmetgltwaaaserglygrucysgruqmlneuficgnfio 320

Qy	321	SerProValLeuSerPheLysGlyGlyLysAsnArgValArgLeuGlnLysLeuArg	340
Db	1077	AGTCCTGTACTTCTTTCAGGGGGGGCAAAAATAGACTCAGGTCTCCACGAACTGAGG	1136
Qy	341	GlnAsnLysLeuGlyGluHisProAlaGlyArgLysArgCysProGlyLeuAsnArgSer	360

[illegible]

RESULTS
AAS17746
ID AAS17746 standard; DNA; 3143 BP.
XX

AC
XX
XX
DT
XX

XX Human; ds; P2Y-like G protein-coupled receptor; GPCR; COPD;
KW Human; ds; P2Y-like G protein-coupled receptor; GPCR; COPD;
KW Chronic obstructive pulmonary disease; nervous system disease;

KW Alzheimer's disease; benign prostatic hyperplasia; urinary incontinence;
KW bacterial infection; fungal infection; protozoan infection;
KW viral infection; pain; cancer; anorexia; bulimia; asthma;

angina pectoris; myocardial infarction; ulcer; inflammation; allergy;
 KW
 psychotic disorder; neurological disorder; anxiety; schizophrenia;
 KW
 manic depression; delirium; severe mental retardation; dyskinesia.
 KW

OS	Homo sapiens.
XX	
XX	
FH	Location/Qualifiers
FH	Key
FH	Key

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XX      DN

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15-NOV-2001.
XX
03-MAY-2001. 2001WC-BE005244
PE

11-MAY-2000; 2000US-0203582P.
21-FEB-2001; 2001US-0269857P.

PA (FARB) BATESK AG.
XX
XX
PI Ramakrishnan S;
XX
XX

DR
DR
REF; 2002-073242/10.
P-ESDB; AAU1251.
XX
PT New polynucleotides for producing P2x-like G protein-coupled receptors

PT like GPCR, especially useful for treating pain, cancer or neurological disorders.
PT
XX

XX The invention relates to an isolated polynucleotide encoding a P2Y₁-like G
CC protein-coupled receptor (GPCR) polypeptide, its fragment, derivative or
CC

RESULT 4
AAS17746

AAS17746
ID AAS17746 standard; DNA; 3143 BP.

XX AC AAS17746:

XX DT 26-FEB-2002 (first entry)

XX DE Human genomic clone for p2Y-like G protein-coupled receptor.

Human; ds; P2Y-like G protein-coupled receptor; GPCR; COPD;
 KW chronic obstructive pulmonary disease; nervous system disease;
 KW Parkinson's disease; multiple sclerosis; dementia; stroke;
 KW Alzheimer's disease; benign prostatic hyperplasia; urinary incontinence;
 KW bacterial infection; fungal infection; protozoan infection;
 KW viral infection; pain; cancer; anorexia; bulimia; asthma;
 KW acute heart failure; hypotension; hypertension; osteoporosis; diabetes;
 KW angina pectoris; myocardial infarction; ulcer; inflammation; allergy;
 KW psychotic disorder; neurological disorder; anxiety; schizophrenia;
 KW manic depression; delirium; severe mental retardation; dyskinesia.

XX
OS Homo sapiens.

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FT	520..2498
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FT	

XX PN WO200185764-A2.

XX
15-NOV-2001.
PD

XX
PF 09-MAY-2001: 2001WO-EP0005244.

XX
PR 11-MAY-2000: 2000US-0203582P.

PR 21-FEB-2001; 2001US-026985/P.
XX

PA (FARB) BAYER AG,
-XX

PI Ramakrishnan S;
XX

DR WPI; 2002-075242/10.
 PR P-PSOB: AUM1251

XX New polynucleotides for producing P2Y-like G protein-coupled receptors
PT (GPCR) that are used for screening inhibitors or regulators of human P2Y-
PT like GPCR, especially useful for treating pain, cancer or neurological
PT disorders.

XX
PS
Dictionnaire: Fig 1: 114nn: English

CC The invention relates to an isolated polynucleotide encoding a p2y-like G
CC protein-coupled receptor (GPCR) polypeptide, its fragment, derivative or
CC

DD 976 CAGGCTGCTGGCCACACTGGGCTTCTCCCAACAGGACATACAATCAATGGCCAGAATCTGG 107

PT Novel G protein-coupled receptor polypeptides including galanin receptor

117 ATGCTGTCATTTGTTCTTCTCCAGGGAAGCAGAAAGCGGAGCGCTGAGAGCTCTG 176
61 CTCCTGGAGGAGCTCCCGGACATGGAGAGGTGGACATGAATACATCACAGGAACA 120
177 CTCCTGGAGGAGCTCCCGGACATGGAGAGGTGGACATGAATACATCACAGGAACA 236
121 GATCTCTGCGAGTTCTCAGAGAGTAAAGCAAGTCTACCTCTCCCTGGCCTTACAGTATC 180
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297 ATCTTATCTAGGCTGCGACCTAAATGGACATGCTTGTGGCACTCTGGGGCCAAACC 356
241 AAGCGTGTGAGCTGTCGCCACCACTATCTGTGTGAACCTGATGTGGCCGACCTGCTTAT 300
357 AAGCGTGTGAGCTGTCGCCACCACTATCTGTGTGAACCTGATGTGGCCGACCTGCTTAT 416
301 GTGCTATGTCCTTCTCATCATCACTACTACTAGATGACAGTGTGGCCCTTCGGGGAG 360
417 GTGCTATGTCCTTCTCATCATCACTACTACTAGATGACAGTGTGGCCCTTCGGGGAG 476
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1137 CAGAACAGTTGGGTGAGCATCTCAGCTGGGAGGAGAGATGCCAGGGTTGACATCT 1196
1081 GG 1082

Db 1197 GG 1198
RESULT 4
AAS17746
ID AAS17746 standard; DNA; 3143 BP.
XX AAS17746;
AC AC
XX 26-FEB-2002 (first entry)
XX Human genomic clone for P2Y-like G protein-coupled receptor.
DE Human; ds; P2Y-like G protein-coupled receptor; GPCR; COPD;
XX chronic obstructive pulmonary disease; nervous system disease;
KW Parkinson's disease; multiple sclerosis; dementia; stroke;
KW Alzheimer's disease; benign prostatic hyperplasia; urinary incontinence;
KW bacterial infection; fungal infection; protozoan infection;
KW viral infection; pain; cancer; anorexia; bulimia; asthma;
KW acute heart failure; hypotension; hypertension; osteoporosis; diabetes;
KW angina pectoris; myocardial infarction; ulcer; inflammation; allergy;
KW psychotic disorder; neurological disorder; anxiety; schizophrenia;
KW manic depression; delirium; severe mental retardation; dyskinesia.
XX Homo sapiens.
XX
XX Key Location/Qualifiers
FH CDS 520..2498
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FT /product= "P2Y-like GPCR"
XX WO200185764-A2.
XX 15-NOV-2001.
XX 09-MAY-2001; 2001WO-EP005244.
XX 11-MAY-2000; 2000US-0203582P.
XX 21-FEB-2001; 2001US-0269857P.
XX (FARB) BAYER AG.
XX Ramakrishnan S;
XX WPI; 2002-075242/10.
XX P-PSDB; AAU11251.
XX New polynucleotides for producing P2Y-like G protein-coupled receptors (GPCR) that are used for screening inhibitors or regulators of human P2Y-like GPCR, especially useful for treating pain, cancer or neurological disorders.
XX Disclosure; Fig 1; 114pp; English.
XX The invention relates to an isolated polynucleotide encoding a P2Y-like G protein-coupled receptor (GPCR) polypeptide, its fragment, derivative or allele, a host cell containing an expression vector comprising the polynucleotide and screening for agents that regulate the GPCR activity. The polynucleotide is useful for producing P2Y-like GPCR polypeptide, which may be employed for screening agents that inhibit or regulate human P2Y-like GPCR. The reagent or inhibitor of the human P2Y-like GPCR is useful for treating or ameliorating P2Y-like GPCR disorders, particularly COPD (chronic obstructive pulmonary disease), peripheral or central nervous system disease (e.g. Parkinson's disease, multiple sclerosis, dementia, stroke, Alzheimer's disease and many other diseases and disorders listed in the specification), benign prostatic hyperplasia or urinary incontinence. A pharmaceutical composition containing the modulators and/or regulators of P2Y-like GPCR is useful for modulating the activity of a P2Y-like GPCR. In particular, these are useful for treating, preventing or ameliorating infections (e.g. bacterial, fungal, protozoan or viral infections), pain, cancer, anorexia, bulimia, asthma, acute heart failure, hypotension, hypertension, osteoporosis, diabetes, angina pectoris, myocardial infarction, ulcers, inflammation, allergies,

DB	Seq	Gene	Location/Qualifiers
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1081	GG 1082		
1516	GG 1517		
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AD116629			
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XX	Human NOVX cDNA to treat human pathological conditions SeqID165.		
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XX	inflammation; autoimmune disorder; allergy; blood disorder;		
XX	acquired immunodeficiency syndrome; AIDS; obesity; asthma;		
XX	immunoglobulin (IgA) nephropathy; cirrhosis; arthritis;		
XX	Alzheimer's disease; infection; stroke; muscular dystrophy; epilepsy;		
XX	cytostatic; cardiac; antiinflammatory; immunosuppressive; antiallergic;		
XX	haemostatic; anti-HIV; antidiabetic; antiarteriosclerotic; anorectic;		
XX	antiasthmatic; nephrotropic; antiarthritic; hepatotropic;		
XX	neuroprotective; nootropic; antibacterial; virucide; antiparasitic;		
XX	relaxant; anticonvulsant; neurogenesis; wound healing; angiogenesis;		
XX	chromosome mapping; tissue typing; pharmacogenomic;		
XX	single nucleotide polymorphism; SNP.		
XX	Homo sapiens.		
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XX	WO200268649-A2.		
XX	06-SEP-2002.		
XX	31-JAN-2002; 2002WO-US02785.		
XX	31-JAN-2001; 2001US-0265495P.		
XX	31-JAN-2001; 2001US-0265412P.		
XX	31-JAN-2001; 2001US-0265513P.		
XX	02-FEB-2001; 2001US-0265517P.		
XX	05-FEB-2001; 2001US-0266406P.		
XX	07-FEB-2001; 2001US-0266767P.		
XX	07-FEB-2001; 2001US-0266975P.		
XX	08-FEB-2001; 2001US-0267057P.		
XX	09-FEB-2001; 2001US-0267459P.		
XX	15-FEB-2001; 2001US-0267823P.		
XX	26-FEB-2001; 2001US-0268974P.		
XX	27-FEB-2001; 2001US-0271664P.		
XX	27-FEB-2001; 2001US-0271839P.		
XX	02-MAR-2001; 2001US-0271855P.		
XX	02-MAR-2001; 2001US-0272788P.		
XX	02-MAR-2001; 2001US-0273046P.		
XX	14-MAR-2001; 2001US-0275925P.		
XX	14-MAR-2001; 2001US-0275947P.		
XX	14-MAR-2001; 2001US-0275950P.		